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Serial No. 09/387,340

-2-

In claim 14, sub-paragraph (a), line 9, please add the word --to-- in front of the phrase "about position 183".

REMARKS

Reconsideration of the above-identified application is respectfully requested in view of the amendments above and the discussion that follows.

Claims 13 and 16 have been cancelled without prejudice in view of the election, and claims 11 and 14 have been amended. Claims 11, 12, 14 and 15 are in the case and before the Examiner.

A. Election

Claim Group III (claims 11, 12, 14, and 15) are hereby formally elected. The previously-made traverse is hereby withdrawn.

B. The Amendments

Claims 11 and 14 have been amended pursuant to the Examiner's helpful suggestions. It is seen that those amendments add no new matter.

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Serial No. 09/387,340

-3-

C. Double Patenting

Claims 11 and 12 were provisionally rejected under the judicially created doctrine of so-called obviousness-type double patenting over claims of co-pending application Serial No. 08/934,367. This provisional rejection is respectfully traversed.

Application Serial No. 08/934,367 has not yet been indicated to be allowable. That being the case, it is submitted that this issue of judicially created double patenting is thus not ripe as to this application. It is submitted that this rejection should be withdrawn.

D. Rejection Under 35 U.S.C. § 112, Second Paragraph

Claims 11, 12, 14 and 15 were rejected under the second paragraph of Section 112 as allegedly being indefinite. Three of the four bases for that alleged indefiniteness have been made moot by the present amendments. The fourth basis cannot be agreed with and this rejection is respectfully traversed regarding use of the term "essentially" as discussed below.

The word "essentially" of claim 14 was asserted to be indefinite. It is to be noted that the complained of word is

not used in a vacuum, but rather as part of the expression "consists essentially".

As such, counsel searched the USPTO data base for use of the phrase "consists essentially" in patent claims. That search located 18,503 presumptively valid, definite U.S patents that used that phrase. A copy of that search is enclosed as Exhibit A. A similar search of the same data base for the word "essentially" used in claims found 128,286 presumptively valid, definite U.S. patents whose claims used the complained of word. A copy of that search is enclosed as Exhibit B. It is therefore submitted that "essentially" as used herein is not indefinite, and that this rejection should be withdrawn.

E. Rejection Under 35 U.S.C. § 112, First Paragraph

Claims 11, 12, 14 and 15 were also rejected under the first paragraph of Section 112 as allegedly lacking enablement. After asserting the unpredictability of the claimed method, the Action took the applicants' data to task by asserting that the lack of a particular level of statistical significance indicated practice of the claimed method would require undue experimentation and therefore that the claimed method lacked

enablement. This basis for rejection cannot be agreed with and is hereby respectfully traversed.

The Action asserts that it is well known in the art that the "p value from a Student's T test should be less or equal to 0.05 to [be] significant." It is respectfully submitted that the p value is itself the measure of significance.

Here, it is seen that all of the disclosures of the application, including the values of p, show that it is more likely than not that the CETP immunogens raised the HDL value compared to the control immunogen. Whether one would desire a greater significance and smaller p value for publication in a refereed journal or for submission to the FDA is not relevant here. Rather, what is relevant is whether a person of ordinary skill in this art would see the disclosures as a whole as a reasonable evidentiary showing that the immunization was successful. It is submitted that the application's disclosures provide such a showing.

Inasmuch as the disclosures of Table 1 of the application indicate to a skilled worker that it is more likely than not that immunizations led to the observed increases in HDL, use of a CETP immunogenic sequence as part of a fusion

protein with HBcAg would likewise be expected to provide an immunogenic polypeptide. As such, undue experimentation is not required here. Rather, all that is needed is for a skilled worker to follow the disclosures of the application to be able to make and use the immunogen of the claims. It is thus submitted that this rejection should be withdrawn.

F. Summary

Claims 13 and 16 have been cancelled without prejudice in view of the election, and claims 11 and 14 have been amended. Each basis for rejection has been dealt with and made moot or otherwise overcome.

It is believed that this application is in condition for allowance of all of the claims. An early notice to that effect is earnestly solicited.

No further fee or petition is believed to be necessary. However, should any further fee be needed, please charge our Deposit Account No. 23-0920, and deem this paper to be the required petition.

The Examiner is requested to phone the undersigned should any questions arise that can be dealt with over the phone to expedite this prosecution.

Respectfully submitted,

By   
Edward P. Gamson, Reg. No. 29,381

Enclosures  
Exhibits A and B

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CERTIFICATE OF MAILING

I hereby certify that this Response and its Exhibits A and B are being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231 on July 10, 2000.

  
Edward P. Gamson